

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION |) | |
| _____ |) | MDL NO. 1203 |
| |) | |
| THIS DOCUMENT RELATES TO: |) | |
| |) | |
| SHEILA BROWN, et al. |) | |
| |) | |
| v. |) | CIVIL ACTION NO. 99-20593 |
| |) | |
| AMERICAN HOME PRODUCTS CORPORATION |) | |

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

November 20, 2007

Before the court is the motion of Linda S. Clark ("Ms. Clark") to deem her privately-obtained echocardiogram as timely under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth.¹ Ms. Clark failed to obtain an echocardiogram before January 3, 2003, the deadline for submitting a privately-obtained echocardiogram.² She, however, maintains that her delay was due to "excusable neglect."

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. The January 3, 2003 deadline marked the end of the original Screening Period, which was the 12-month period beginning on the date of Final Judicial Approval (Jan. 2, 2002). See Settlement Agreement § I.49. To receive Matrix Compensation Benefits ("Matrix Benefits"), the Settlement Agreement required Class Members who chose not to participate in the Screening Program to obtain an echocardiogram between the commencement of diet drug use and the end of the Screening Period. See id. at § IV.B.1.a.

I.

According to Ms. Clark's motion and accompanying affidavits, she was prescribed and took the diet drugs commonly known as fen-phen³ from approximately April 1996 to June 1997 as part of a 14-month Fen-Phen clinical trial.⁴ In April 2000, Ms. Clark's physician's assistant informed her that she had a heart murmur. Ms. Clark questioned the significance of the heart murmur, but she was told that it was minor and not to be concerned. Ms. Clark continued to see her physician on a regular basis and frequently complained of fatigue and occasionally shortness of breath. In March 2002, her physician's assistant again noted the heart murmur. Ms. Clark questioned whether Pondimin® caused the heart murmur, but she was advised that she suffered only from stress. Her requests for a referral to see a heart specialist were deemed not necessary, and her physician refused her requests as late as December 2002.

At that point, Ms. Clark decided to switch family physicians. Her new physician referred her to a heart specialist. Ms. Clark subsequently received a transthoracic

3. "Fen-Phen" is widely used to refer to the combination of the diet drugs Fenfluramine and Phentermine. Fenfluramine, marketed under the brand name Pondimin®, and the later related drug Dexfenfluramine, marketed under the brand name Redux™, were sold by Wyeth and are the subject of the Settlement Agreement. Ms. Clark states that she was prescribed Pondimin®.

4. Ms. Clark signed a consent and release form stating that she was informed of the risks of Pondimin® prior to participating in the Fen-Phen clinical trial study. See Consent and Release form, attached to Wyeth's response.

echocardiogram on March 20, 2003, a heart catheterization on March 27, 2003, and a transesophageal echocardiogram on April 14, 2003. Ms. Clark's new physicians diagnosed her with aortic insufficiency and stenosis, and, on April 21, 2003, she underwent aortic valve replacement surgery.

On May 2, 2003, Ms. Clark submitted a timely Blue Form⁵ to the Trust, and she submitted a Green Form⁶ in November 2003.⁷ By letter dated February 7, 2005, the Class Counsel Claims Office notified Ms. Clark that her claim would not be processed by the Trust because her echocardiogram had not been performed prior to the Screening Period deadline. Three months after receiving the notice that her claim was untimely, Ms. Clark filed the present motion. Ms. Clark claims that her initial physician's refusal to refer her for an echocardiogram constitutes excusable neglect.

II.

The Settlement Agreement approved by this court in PTO No. 1415 provides strict deadlines for Class Members to seek

5. The Blue Form is one of the forms available to Class Members to register for Matrix Benefits with the Trust. The deadline for submitting the form was May 3, 2003. See Pretrial Order ("PTO") No. 3253 (Feb. 12, 2004).

6. Under the Settlement Agreement, Class Members are required to complete the Green Form, in addition to the Blue Form, to receive Matrix Benefits from the Trust.

7. Ms. Clark was *pro se* when she submitted these forms.

Matrix Benefits⁸ from the Trust. The Settlement Agreement provides, in part:

The following Class Members, and only such Class Members, shall be entitled to the compensation benefits from Fund B ("Matrix Compensation Benefits"):

- a. Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive or as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period [Jan. 3, 2003] and who have registered for further settlement benefits by Date 2 [May 3, 2003]

Settlement Agreement § IV.B.1.a. (emphasis added).

This Settlement Agreement provision imposes two deadlines on Class Members. First, Class Members who did not participate in the Screening Program⁹ were required to obtain a private echocardiogram and consequently have been diagnosed with

8. Matrix Benefits are payable from Fund B, created in the Settlement Agreement to compensate Class Members who have developed Matrix-level conditions, or will develop those conditions in the future. Settlement Agreement § IV.B.-C.

9. The Screening Program provided Transthoracic Echocardiograms and associated interpretive physician benefits to eligible Class Members. Settlement Agreement § I.50. See also id. at §§ IV.A.1.a. & IV.A.2.b. Diet Drug Recipients who ingested Pondimin® or Redux™ for 61 days or more and had not obtained a qualifying echocardiogram prior to September 30, 1999 were eligible for the Screening Program. See id. at §§ II.C.1.(b) & IV.A.1.a.; see also Official Court Notice, p. 5. In PTO No. 2677, we extended the deadline for the Screening Program to July 3, 2003. The extension applied only to claimants who timely registered for the Screening Program, but for whom the Trust, given the significant volume of claims awaiting processing, could not ensure that they would receive a Screening Program echocardiogram by the January 3, 2003 deadline. See PTO No. 2677, at 9-10 (Dec. 10, 2002).

FDA Positive or Mild Mitral Regurgitation between the time they began using diet drugs and January 3, 2003. Second, Class Members were required to register with the Trust by May 3, 2003. Although Ms. Clark met the second deadline by submitting a Blue Form on May 2, 2003, she failed to obtain a private echocardiogram by January 3, 2003. Class Members must meet both deadlines to be eligible for Matrix Benefits.

The deadlines imposed by the Settlement Agreement may be extended if the movant can show his or her failure to meet the deadlines was due to "excusable neglect." In In re Orthopedic Bone Screw Prods. Liab. Litig., 246 F.3d 315, 323 (3d Cir. 2001), our Court of Appeals reiterated the Supreme Court's analysis of excusable neglect as set forth in Pioneer Inv. Servs. Co. v. Brunswick Assocs. Ltd., 507 U.S. 380, 395 (1993). Four factors should be evaluated when deciding whether excusable neglect exists: (1) the danger of prejudice to the non-movant; (2) the length of the delay and its potential effect on judicial proceedings; (3) the reason for the delay, including whether it was within the reasonable control of the movant; and (4) whether the movant acted in good faith. Pioneer, 507 U.S. at 395; Bone Screw, 246 F.3d at 322-23. We shall discuss each of these factors in turn.

Under the first prong of Pioneer, we must determine the danger of prejudice to the non-movants should the requested extension be granted. See id. Ms. Clark argues that Wyeth and the Trust would not be prejudiced because she is just one

claimant asking for benefits for which she would otherwise be entitled. She argues that her circumstances are unique because her delay in submitting a timely echocardiogram is the result of medical malpractice.

The finality provided by the Settlement Agreement to Wyeth, the Trust and other Class Members has been of paramount importance throughout the administration of the Settlement Agreement. Finality is not only important to Wyeth, but also to the Trust so that it can consider applications for Matrix Benefits and provide those benefits to injured Class Members in a timely manner. If Ms. Clark's motion were the only one of its kind, her late registration may pose little danger of prejudice to the non-movants. Ms. Clark, however, is certainly not the only Class Member who did not receive a referral for an echocardiogram. While this may seem severe, Ms. Clark's circumstances are neither unique nor particular to her as it is not uncommon for a physician to decline a patient's referral request. "Although the admission of any particular claimant may not in itself cause a substantial drain on the Trust, allowing this claimant to escape the firm deadlines set forth in the Settlement Agreement ... will surely encourage others to seek the same relief." PTO No. 3923, at 3.

Second, we must consider the length of the delay and its effect on judicial proceedings. Pioneer, 507 U.S. at 395; Bone Screw, 246 F.3d at 322-23. Ms. Clark argues that obtaining an echocardiogram on March 20, 2003 was an insignificant delay

from the Screening Period deadline with no effect on the administration of the Settlement Agreement. The January 3, 2003 deadline to obtain a private echocardiogram, however, was not an arbitrary date. This date was carefully chosen in light of evidence that the later the diagnosis, the greater the likelihood that the Class Member's valve damage was not caused by diet drugs. In re Diet Drugs, 2000 WL 1222042, at *46-47 (E.D. Pa. Aug. 28, 2000). Diet drug induced valve regurgitation is not latent and can be detected by an echocardiogram after the Class Member ceases use of the drugs. Id. By January 3, 2003, Class Members who chose not to register for Screening Program benefits had five years to obtain a private echocardiogram. See PTO No. 2677 at 13 (Dec. 10, 2003). In Ms. Clark's case, she did not have an echocardiogram until more than two months after the deadline to obtain a private echocardiogram had passed. This is not an insignificant amount of time.

Moreover, Ms. Clark did not seek relief to submit her late echocardiogram until May 2005. Ms. Clark argues that her delay was caused by the failure of the Class Counsel Claims Office to recognize timely that she would be disqualified for Matrix Benefits.¹⁰ Ms. Clark, however, had actual notice of the January 3, 2003 deadline when she submitted the Blue Form on

10. Ms. Clark provides no explanation for her three-month delay in seeking relief after receiving notice from the Class Counsel Claims Office in February 2005.

May 2, 2003.¹¹ At that point, Ms. Clark should have sought relief to submit her late echocardiogram as timely. To allow Ms. Clark an extension to seek relief would undermine the finality of the Settlement Agreement and open the floodgates to similarly situated Class Members who are presently time-barred.

Under the third prong, we must review Ms. Clark's reason for the delay. Pioneer, 507 U.S. at 395; Bone Screw, 246 F.3d at 322-23. Ms. Clark argues that it was reasonable for her to rely on the advice of her physician and that obtaining an echocardiogram within the Screening Period deadline was not within her control. We disagree. Ms. Clark voluntarily chose to be treated by her family physician and to remain under this physician's care despite her unheeded concern over a two-year period that the diet drugs may have caused her symptoms. Ms. Clark was aware of the risks associated with Pondimin®, as evidenced by questioning her physician's assistant that Pondimin® may be the cause of her symptoms and by the release form that she signed in April 1996 prior to participating in a 14-month Fen-Phen clinical trial. Indeed, the "Consent and Release" form stated: "My physician has disclosed to me that these medications are being used in a 'non-label' manner and has disclosed to me

11. Claimants, such as Ms. Clark, who took diet drugs for 61 or more days, must complete the Blue Form to register for Settlement Benefits. The Blue Form specifically states that, if electing to receive \$6,000 in cash or \$10,000 in heart valve-related medical services, a claimant must be diagnosed as FDA Positive by the end of the Screening Period (January 3, 2003). See Blue Form; see also Official Court Notice, p. 5.

the risks involved with these medications." See Consent and Release form, attached to Wyeth's response as an exhibit.

Moreover, Ms. Clark should have been aware of her rights under the Settlement Agreement through the extensive notice provided by the Nationwide Notice Plan. The Official Court Notice sent to Class Members states that:

Diet Drug Recipients who have been diagnosed with serious heart valve disease ... are eligible for Compensation Payments ... if ... [t]he Class Member is a [Diet Drug Recipient] who has been diagnosed by a qualified physician as (i) FDA Positive or (ii) as having Mild Mitral Regurgitation with an eligible echocardiogram performed between the start of Pondimin and/or Redux use and the end of the Screening Period [Jan. 3, 2003] [and] has registered for further Settlement Benefits within 120 days of the close of the Screening Period [May 3, 2003].

Official Court Notice, p. 7 (emphasis added). Notice of the Settlement Agreement complied with Rule 23 of the Federal Rules of Civil Procedure, which states: "For any class certified under Rule 23(b)(3), the court must direct to class members the best notice practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort." Fed. R. Civ. P. 23(c)(2)(B). The Nationwide Notice Plan was put in place to inform all Class Members of the Settlement Agreement. See PTO No. 1415, at 79-87. We have stated previously that the notice plan was the "best notice practicable under the circumstances" and concluded that it was "highly successful." PTO No. 997 ¶ 15 at 8; PTO No. 1415 at 83. Analysis of the notice plan concluded that "97% of women between

the ages of 25 and 54 viewed one or more forms of televised or printed notice an average of 10 times." PTO No. 1415 at 22. The Nationwide Notice Plan put Ms. Clark on constructive notice that she should obtain an echocardiogram prior to suffering any symptoms and, in any event, prior to the January 3, 2003 deadline.

To the extent that Ms. Clark argues that the price of a private echocardiogram precluded her from obtaining one without a referral, the Settlement Agreement allowed Class Members to acquire free echocardiograms through the Trust Screening Program by registering prior to August 1, 2002, or to seek reimbursement for privately-obtained echocardiograms. See Settlement Agreement §§ IV.A.1.a. & IV.A.1.b; see also Official Court Notice, p. 5; Blue Form, pp. 1, 12 (register for Screening Program), White Form, p. 1 (request for reimbursement of private echocardiogram). After first questioning whether Pondimin® caused her heart murmur in March 2002, Ms. Clark could have obtained a free echocardiogram through the Screening Program by registering prior to the August 1, 2002 deadline. Therefore, although her family physician may not have referred her to a heart specialist prior to January 3, 2003, Ms. Clark certainly could have taken advantage of the Screening Program or sought reimbursement benefits for a private echocardiogram.

Finally, we have no reason to doubt that Ms. Clark acted in good faith. However, the danger of prejudice to non-movants and the length of, and reasons for, the delays weigh

heavily in favor of finding that Ms. Clark's actions do not constitute excusable neglect. Accordingly, Ms. Clark is not entitled to submit a late echocardiogram for purposes of seeking benefits under the Settlement Agreement.

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AND NOW, on this 20th day of November, 2007, for the reasons stated in the accompanying Memorandum, it is hereby ORDERED that the motion of Linda S. Clark to submit her privately-obtained echocardiogram as timely under the Settlement Agreement is DENIED.

BY THE COURT:

/s/ Harvey Bartle III

C.J.